

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION**

UNITED STATES OF AMERICA and)	
THE STATE OF TENNESSEE <i>ex. rel.</i>)	
SUZANNE ALT, <i>et al.</i> ,)	Case No.: 3:16-cv-0549
)	(Consolidated)
Plaintiffs,)	
)	JUDGE TRAUGER
v.)	
)	JURY DEMAND
ANESTHESIA SERVICES ASSOCIATES,)	
PLLC, <i>et al.</i> ,)	
)	
Defendants.)	

**ANSWER OF DEFENDANT ANESTHESIA SERVICES ASSOCIATES, PLLC TO THE
CONSOLIDATED COMPLAINT IN INTERVENTION**

Defendant Anesthesia Services Associates, PLLC, d/b/a Comprehensive Pain Specialists (“CPS”) answers the United States’ and the State of Tennessee’s Consolidated Complaint in Intervention (Docket No. 65) as follows:

I. No response required.

1. CPS admits that the United States and the State of Tennessee purport to bring certain statutory and common law claims against CPS, but denies that such claims have merit. The remaining allegations in paragraph 1 are denied.

2. Admitted.

3. CPS admits that Dickerson, Carrero, and Kroll are some, but not all, of the physician-owners of CPS, and admits that during his tenure as CEO, Davis did oversee the day to day operations of CPS. The remaining allegations in paragraph 3 are denied.

4. Denied.

5. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 5 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

6. Denied.

7. CPS admits that Davis adopted various employee bonus programs during his tenure as CEO, but deny that the Owners had knowledge of the details of all of the various bonus programs adopted by Davis.

8. CPS admits that Davis entered into an Employment Agreement with Smith on behalf of CPS, and that the terms of that Employment Agreement speak for themselves. CPS admits that Smith improperly asserted pressure on some of the providers at his clinics to order certain services and devices, and for that reason, among others, CPS terminated Smith's Employment Agreement on June 27, 2017.

9. CPS admits that it discovered, after Davis' termination, that Davis may have changed codes submitted by providers, but CPS does not know how often such conduct may have occurred or what, if any, impact on reimbursement it may have had. CPS denies that any such conduct by Davis was authorized by the Company or its Owners.

10. Denied.

11. Denied.

12. CPS admits that Davis was convicted of one count of conspiracy and seven counts of violating the Ant-Kickback Statute in connection with a side deal that he entered into with the owner of CCC Medical in his private capacity. CPS denies that the unlawful conduct for which Davis was convicted involved or benefited the Company in any way. As set forth in the Indictment, CPS was a victim of the charged conduct.

13. Denied.

14. Denied.

15. Denied.

16. Denied.

17. Denied.

18. Denied.

II. No response required.

19. Denied.

20. CPS admits that all Defendants appear to reside in or operate in Tennessee. CPS denies that the events or omissions giving rise to the claims alleged occurred in this District or at all.

III. No response required.

21. Admitted.

22. Admitted.

23. CPS denies that it began “dissolution proceedings.” The remaining allegations in paragraph 23 are admitted.

24. CPS admits the allegations in the first two sentences of paragraph 24. CPS denies the second two sentences of paragraph 24, and affirmatively avers that Carrero joined Anesthesia Services Associates, PLLC in 2004 (before the creation of CPS), but did not have an ownership interest until later, and that he first served on the CPS Board of Directors in January 2018.

25. Admitted.

26. Defendant Dickerson stepped down from the CPS Board of Directors in December 2017. The remaining allegations in paragraph 26 are admitted.

27. CPS denies that Kroll's Kentucky medical license has been deactivated. The remaining allegations in paragraph 27 are admitted.

28. Admitted.

IV. No response required.

A. No response required.

29. The allegations in paragraph 29 recite a portion of a federal statute, and therefore, no response is required. To the extent that a response is required, CPS denies any characterization of the statute and states that the statute speaks for itself.

30. The allegations in paragraph 30 recite a portion of a federal statute, and therefore, no response is required. To the extent that a response is required, CPS denies any characterization of the statute and states that the statute speaks for itself.

31. The allegations in paragraph 31 are legal conclusions to which no response is required. To the extent a response is required, CPS denies any characterization of the statute and states that the statute speaks for itself.

B. No response required.

32. The allegations in paragraph 32 recite a portion of a state statute, and therefore, no response is required. To the extent that a response is required, CPS denies any characterization of the statute and states that the statute speaks for itself.

C. No response required.

33. Admitted.

34. CPS generally admits the allegations in paragraph 34, but denies that Medicare Administrative Contractors ("MACs") are referred to as "fiscal intermediaries," as they were formerly, and denies that MACs pay all claims submitted by health care providers.

35. The allegations in paragraph 35 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the cited sources speak for themselves and denies the allegations in paragraph 35 to the extent they mischaracterize the sources' language, meaning, or application.

36. The allegations in paragraph 36 purport to characterize a portion of a federal regulation, and therefore, no response is required. To the extent that a response is required, CPS denies any characterization of the regulation and states that the regulation speaks for itself.

37. The allegations in paragraph 37 recite a portion of a federal regulation, and therefore, no response is required. To the extent that a response is required, CPS denies any characterization of the regulation and states that the regulation speaks for itself.

38. CPS admits that the Medicare program consists of four parts: A, B, C, and D. CPS denies the remaining allegations in paragraph 38.

39. The allegations in paragraph 39 are legal conclusions to which no response is required. To the extent a response is required, CPS states that the Medicare statute speaks for itself and denies the allegations in paragraph 39 to the extent they mischaracterize the Medicare statute's language, meaning or application.

40. Admitted.

41. Admitted.

42. Admitted.

43. Admitted.

44. Admitted.

45. The allegations in paragraph 45 purport to characterize portions of a federal regulation and policy manual, and therefore, no response is required. To the extent that a response

is required, CPS denies the allegations in paragraph 45 to the extent they mischaracterize the regulation and policy manual, and states that the regulation and policy manual speak for themselves.

46. The allegations in paragraph 46 recite portions of a federal regulation, and therefore, no response is required. To the extent a response is required, CPS denies the allegations in paragraph 46 to the extent they mischaracterize the regulation, and states that the regulation speaks for itself.

47. The allegations in paragraph 47 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the cited sources speak for themselves and denies the allegations in paragraph 47 to the extent they mischaracterize the sources' language, meaning, or application.

48. CPS admits the allegations in paragraph 48, upon information and belief.

49. The allegations in paragraph 49 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the cited sources speak for themselves and denies the allegations in paragraph 49 to the extent they mischaracterize the sources' language, meaning, or application.

50. The allegations in paragraph 50 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the cited sources speak for themselves and denies the allegations in paragraph 50 to the extent they mischaracterize the sources' language, meaning, or application.

51. Admitted.

52. The allegations in paragraph 52 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the cited sources speak for

themselves and denies the allegations in paragraph 52 to the extent they mischaracterize the sources' language, meaning, or application.

53. The allegations in paragraph 53 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the cited sources speak for themselves and denies the allegations in paragraph 53 to the extent they mischaracterize the sources' language, meaning, or application.

54. The allegations in paragraph 54 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the applicable statutes and regulations speak for themselves and denies the allegations in paragraph 54 to the extent they mischaracterize the statutes' or regulations' language, meaning, or application.

55. The allegations in paragraph 55 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the cited sources speak for themselves and denies the allegations in paragraph 55 to the extent they mischaracterize the sources' language, meaning, or application.

56. The allegations in paragraph 56 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the applicable statutes and regulations speak for themselves and denies the allegations in paragraph 56 to the extent they mischaracterize the statutes' or regulations' language, meaning, or application.

57. The allegations in paragraph 57 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the applicable statutes and regulations speak for themselves and denies the allegations in paragraph 57 to the extent they mischaracterize the statutes' or regulations' language, meaning, or application.

58. The allegations in paragraph 58 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the cited sources speak for themselves and denies the allegations in paragraph 58 to the extent they mischaracterize the sources' language, meaning, or application.

59. The allegations in paragraph 59 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the cited sources speak for themselves and denies the allegations in paragraph 59 to the extent they mischaracterize the sources' language, meaning, or application.

60. The allegations in paragraph 60 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the cited sources speak for themselves and denies the allegations in paragraph 60 to the extent they mischaracterize the sources' language, meaning, or application.

61. The allegations in paragraph 61 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the cited sources speak for themselves and denies the allegations in paragraph 61 to the extent they mischaracterize the sources' language, meaning, or application.

62. The allegations in paragraph 62 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the cited sources speak for themselves and denies the allegations in paragraph 62 to the extent they mischaracterize the sources' language, meaning, or application.

63. The allegations in paragraph 63 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the cited sources speak for

themselves and denies the allegations in paragraph 63 to the extent they mischaracterize the sources' language, meaning, or application.

64. Admitted.

65. CPS admits that the CMS Form 1500 and 837P form contain certifications, the content of which speak for themselves.

66. The allegations in paragraph 66 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the cited sources speak for themselves and denies the allegations in paragraph 66 to the extent they mischaracterize the sources' language, meaning, or application.

67. The allegations in paragraph 67 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the cited sources speak for themselves and denies the allegations in paragraph 67 to the extent they mischaracterize the sources' language, meaning, or application.

68. CPS admits that CMS Form 1500 contains certifications and notices, which provisions speak for themselves.

69. CPS admits that the various MACs utilize enrollment applications, the contents of which speak for themselves.

70. The allegations in paragraph 70 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the cited sources speak for themselves and denies the allegations in paragraph 70 to the extent they mischaracterize the sources' language, meaning, or application.

71. The allegations in paragraph 71 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the cited sources speak for

themselves and denies the allegations in paragraph 71 to the extent they mischaracterize the sources' language, meaning, or application.

72. The allegations in paragraph 72 purport to describe the contents of a written contract, the contents of which speak for itself.

73. The allegations in paragraph 73 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the cited sources speak for themselves and denies the allegations in paragraph 73 to the extent they mischaracterize the sources' language, meaning, or application.

74. CPS lacks sufficient information concerning the routine payment practices of Federal Healthcare Programs and TennCare, and therefore, denies the same.

V. Denied.

75. Admitted.

76. Admitted.

77. Admitted.

78. Admitted.

79. Admitted.

80. CPS admits that Kroll knew Davis in his role as a medical device sales representative for Medtronic. The remaining allegations in paragraph 80 are denied.

81. CPS admits that Davis was hired as CEO pursuant to an Employment Agreement dated May 20, 2011, the terms of which speak for themselves. CPS denies the remaining allegations in paragraph 81 to the extent that they are inconsistent with the terms of the written Employment Agreement.

82. CPS admits that it had over 60 locations at one time. The remaining allegations in paragraph 82 are denied.

83. Admitted.

84. Denied. Muench joined CPS in 2011.

85. Admitted.

86. Denied. Dickerson stepped down from the board in 2018 and was replaced by Carrero.

87. Admitted.

88. Admitted.

89. CPS admits that during his tenure as CEO, Davis was responsible for negotiating the terms of various contracts, including but not limited to physician employment contracts, lease agreements and other contracts related to acquisitions. CPS lacks sufficient knowledge as to whether Dickerson approved any such contracts, and therefore, denies the same.

90. Denied.

91. CPS admits that Davis negotiated the terms of an Asset Purchase Agreement, dated May 23, 2013, between Smith and CPS, and an Employment Agreement, dated May 23, 2013, between Smith and CPS, the terms of which contracts speak for themselves. The remaining allegations in paragraph 91 are denied.

92. CPS admits that the Owners were entitled to receive 100 percent of their own net revenues and a percentage of the ancillary bonus pool, but denies that the Owners received all the compensation to which they were contractually entitled. For several years, the Owners chose to forego such compensation to allow the Company to retain necessary operating capital. The remaining allegations in paragraph 92 are denied.

VI. Denied.

93. Denied.

94. CPS admits that Davis sent an email to Kroll, Dickerson, Carrero and Arney on August 19, 2011, the contents of which speak for themselves. CPS denies the remaining allegations in paragraph 94, as they mischaracterize the contents of the written email upon which the allegations are purportedly based.

95. Denied.

96. CPS admits that it discovered, after Davis' termination, that Davis may have changed codes submitted by providers, but CPS does not know how often such conduct may have occurred or what, if any, impact on reimbursement it may have had. CPS denies that any such conduct by Davis was authorized by the Company or its Owners, and denies the remaining allegations in paragraph 96.

A. Denied.

97. Denied.

98. Denied.

99. Admitted.

100. CPS denies that it is a "common practice" in the medical community to first order a qualitative test of urine to detect the presence or absence of drugs or metabolites in the sample. The remaining allegations in paragraph 100 are admitted.

101. CPS admits that Point-of-Care testing is reimbursed at a lower rate than testing performed off-site at an actual CLIA-certified lab. The remaining allegations in paragraph 101 are denied.

102. Denied.

103. The allegations in paragraph 103 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the applicable Medicare rules and regulations speak for themselves and denies the allegations in paragraph 103 to the extent they mischaracterize the rules' and regulations' language, meaning, or application.

104. The allegations in paragraph 104 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the applicable federal and state rules and regulations speak for themselves and denies the allegations in paragraph 104 to the extent they mischaracterize the rules' and regulations' language, meaning, or application.

105. CPS admits that some of the MACs have issued sub-regulatory guidance in the form of Local Coverage Determinations ("LCDs") that address urine drug testing in the context of treating patients on opioid therapy. The LCDs are written documents which speak for themselves. The remaining allegations in paragraph 105 are denied.

106. Denied.

107. The allegations in paragraph 107 purport to recite and characterize the terms of a written document, the content of which speaks for itself. To the extent the allegations in paragraph 107 mischaracterize the language, meaning or application of that written document, they are denied.

108. The allegations in paragraph 108 purport to recite and characterize the terms of a written document, the content of which speaks for itself. To the extent the allegations in paragraph 108 mischaracterize the language, meaning or application of that written document, they are denied.

109. The allegations in paragraph 109 purport to recite and characterize the terms of a written document, the content of which speaks for itself. To the extent the allegations in paragraph

109 mischaracterize the language, meaning or application of that written document, they are denied.

110. The allegations in paragraph 110 purport to recite and characterize the terms of a written document, the content of which speaks for itself. To the extent the allegations in paragraph 110 mischaracterize the language, meaning or application of that written document, they are denied.

111. The allegations in paragraph 111 purport to recite and characterize the terms of a written document, the content of which speaks for itself. To the extent the allegations in paragraph 111 mischaracterize the language, meaning or application of that written document, they are denied.

112. The allegations in paragraph 112 purport to characterize the terms of a written document, the content of which speaks for itself. To the extent the allegations in paragraph 112 mischaracterize the language, meaning or application of that written document, they are denied.

113. The allegations in paragraph 113 purport to recite and characterize the terms of a written document, the content of which speaks for itself. To the extent the allegations in paragraph 113 mischaracterize the language, meaning or application of that written document, they are denied.

114. The allegation in paragraph 114 purports to characterize how qualitative testing “was billed” from 2011 to 2015, but does not state who billed qualitative testing in this manner. CPS admits that, beginning January 1, 2011, CMS approved use of HCPCS codes G0431 and G0434 for billing qualitative drug screens and drug screens other than chromatographic, respectively.

115. CPS denies that HCPCS codes G0431 and G0434 “were discontinued” in 2016. CPS admits that, effective January 1, 2016, CMS required the use of HCPCS codes G0477, G0478, or G0479 for presumptive drug testing claims. CPS admits that, effective January 1, 2017, CMS required the use of CPT codes 80305, 80306, or 80307 for presumptive drug testing claims.

116. The allegations in paragraph 116 stated that certain drug screens were “generally” billed using CPT code 84311. CPS is without sufficient information concerning the general practice for billing “CDDP Panels and quantitative testing,” and therefore, denies the same. CPS admits that CPT code 84311 was an approved CPT code by CMS. CPS is without sufficient information concerning the remaining allegations in paragraph 116, and therefore, denies the same.

117. CPS admits that CPT code 80299 is a code for quantitative testing for therapeutic drugs that are not elsewhere specified where the patient in question is on a prescription for the drug in question. CPS admits that CMS approved HCPCS codes G0480 to G0483, effective January 1, 2016, for definitive drug testing claims, where each code corresponds to an increasing number of drug classes tested.

118. The allegations in paragraph 118 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the cited HHS-OIG sub-regulatory guidance speaks for itself and denies the allegations in paragraph 118 to the extent they mischaracterize the language, meaning, or application of the cited OIG Report.

119. The allegations in paragraph 119 purport to characterize the terms of written LCDs, the contents of which speak for themselves. To the extent the allegations in paragraph 119 mischaracterize the language, meaning or application of those LCDs, they are denied.

120. CPS admits that CPT codes 82565, 82570, 82670, 83986, 84075, and 84295 were used for claims relating to chemistry assay panels testing for creatinine (blood), creatinine (other

source), estradiol, alkaline phosphate, and sodium, respectively. CPS admits that these tests were used for specimen validity testing.

b. Denied.

121. Denied.

122. CPS states that, to the extent the allegations in paragraph 122 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 122, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

123. CPS admits that it opened up its own testing facility. The remaining allegations in paragraph 123 are denied.

124. Admitted.

125. CPS admits that it discouraged its providers from using Point-of-Care testing because of its well-documented unreliability as described in the medical literature, including the Tennessee Department of Health, “Tennessee Chronic Pain Guidelines”, which state that Point-of-Care testing has high rates of false positive and false negative results. CPS admits that Point-of-Care testing is reimbursed at a lower rate than testing conducted at an actual CLIA-certified lab.

126. CPS admits that it developed Urine Drug Screening Guidelines, and that the contents of these written documents speak for themselves. CPS admits that the Guidelines recommended drug screening for all new patients on opioid therapy, recommended screening approximately six times a year, and more frequent testing if a patient exhibited red flag or suspicious behavior. CPS admits the Guidelines discouraged the use of Point-of-Care testing because of its well-documented unreliability as described in the medical literature, including the Tennessee Chronic Pain Guidelines, which state that Point-of-Care testing has high rates of false

positive and false negative results. CPS denies that its UDS Guidelines were mandatory, as suggested in the allegations in paragraph 126, as all CPS providers were expected and entitled to use their own clinical judgment in making treatment decisions for their patients.

127. Admitted. The Guidelines were also approved by Muench.

128. Admitted.

129. Denied.

130. Denied.

131. CPS states that, to the extent the allegations in paragraph 131 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 131, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

132. CPS states that, to the extent the allegations in paragraph 132 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 132, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

133. CPS admits that the Owners abided by the UDS Guidelines, in addition to and in conjunction with the exercise of their own independent clinical judgment. The remaining allegations in paragraph 133 are denied.

134. CPS states that, to the extent the allegations in paragraph 134 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 134, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

135. CPS admits that that training manuals were made available to CPS personnel, including a template entitled “Ordering Urine Drug Screens (UDS)”, the content of which speaks for itself. The remaining allegations in paragraph 135 are denied.

136. CPS admits that providers ordered UDS through various methods, including various panels or custom orders, throughout the relevant time period. The remaining allegations in paragraph 136 are denied.

137. CPS admits that “quantitative testing was ordered from the outset” for all new patient on chronic opioid therapy (“COT”), as the Tennessee Chronic Pain Guidelines provide that “confirmation [quantitative] testing is required prior to the outset of COT.” Tennessee Chronic Pain Guidelines, Tennessee Department of Health, p. 34, 3rd ed., 2019. The remaining allegations in paragraph 137 are denied.

138. Admitted, although CPS affirmatively avers that this is the standard of practice for patients on COT who are commonly seen by providers every month as prescriptions for opioids are generally written for a 30 day supply, per DEA guidelines, and that lab tests results are reviewed and used in the patients’ course of treatment during follow-up visits.

139. Denied.

140. CPS denies that Point-of-Care Testing with real time results is important to treating of patients on COT. Rather, the Tennessee Chronic Pain Guidelines suggest that such testing which is more commonly used in the workplace setting is inappropriate in the clinical setting when treating patients on COT because of its well-documented unreliability and high rates of false positive and false negative results. CPS admits that it discouraged the use of Point-of-Care testing because of its clinical inappropriateness and unreliability, as documented in the Tennessee Chronic Pain Guidelines. CPS admits that clinics had access to pre-printed shipping labels to send

specimens to the CPS lab, but denies that at all times during the relevant time period, all clinics did not possess the equipment necessary to perform Point-of-Care testing.

141. Denied.

142. CPS admits that as it acquired more clinics and employed more providers, there was a corresponding increase in lab claims.

143. CPS is without sufficient information concerning the percentage of Medicare reimbursement related to lab claims that Dr. Brummett or Dr. Buenger received prior to joining CPS, and therefore, denies the same.

144. Denied.

145. Denied.

146. Denied.

147. Denied.

148. Denied.

149. Denied.

150. Denied.

c. Denied.

151. CPS is without sufficient information as to what, if anything, raised red flags with CMS, and therefore, denies the same. CPS affirmatively avers that the AdvanceMed audit referred to in paragraph 152 began in 2013 at the Cleveland clinic owned by Smith prior to CPS' acquisition of that clinic.

152. Admitted.

153. Admitted.

154. Denied.

155. CPS admits that AdvanceMed issued its audit results by letter dated March 17, 2015, the content of which speaks for itself.

156. CPS admits that Cahaba issued its Redetermination Notice, dated June 23, 2015, and issued a corrected Redetermination Notice dated July 6, 2015, the contents of which speak for themselves.

157. Admitted.

158. CPS admits that its compliance personnel continually worked to update and revise CPS' UDS Guidelines. CPS admits that its compliance department issued revised UDS Guidelines, effective September 1, 2015, which were approved by Kroll and the content of which speaks for itself. CPS denies the remaining allegations in paragraph 158 to the extent they mischaracterize the content of the September 1, 2015 UDS Guidelines.

159. Admitted.

160. Admitted.

161. Admitted.

162. CPS admits that CPS compliance personnel noted certain instances of overutilization with some providers at the Cleveland clinic. The remaining allegations in paragraph 162 are denied.

163. CPS admits that members of CPS' compliance committee, which included Sarah Trent, conducted training on UDS to providers at the Cleveland clinic to address instances of overutilization that the compliance committee noted in its internal review. The remaining allegations in paragraph 163 are denied.

164. CPS admits that around December 9, 2015, the CPS compliance team issued instructions to providers to limit two-month cycle appointments to conform with DEA guidance

regarding 30 day supply recommendations for prescribing opioids. CPS denies that such instructions had anything to do with UDS, and denies the remaining allegations in paragraph 164.

165. Admitted.

166. Admitted. CPS affirmatively avers that the UDS Guidelines recommendations are fully consistent with the Tennessee Chronic Pain Guidelines.

167. Admitted. CPS affirmatively avers that the Clinical QA Committee recommendations are fully consistent with the Tennessee Chronic Pain Guidelines.

168. Admitted.

169. Admitted.

170. CPS admits that the training provided multiple times by CPS' compliance personnel did not result in the level of improvement that CPS expected from its employees, and therefore, CPS' compliance committee voted to have the East Tennessee providers receive additional training with Dr. Kroll.

171. CPS admits that its compliance personnel had concerns regarding Anita Bayles, and worked continuously to address those concerns with Ms. Bayles.

172. Admitted.

173. CPS admits that Davis made the decision to keep Ms. Bayles on staff because Dr. Niendorff, her supervising physician, promised to supervise Ms. Bayles more closely and to limit her interactions with patients unless Dr. Niendorff was present, and insisted that she needed Ms. Bayles to assist her with managing her busy patient load. CPS denies that Davis' decision to keep Ms. Bayles was based on her ability to generate revenue.

174. CPS admits that Kroll was aware of Davis' decision to keep Ms. Bayles on staff at the request of Dr. Niendorff based on Dr. Niendorff's assurances that she would not allow Ms.

Bayles to see patients without Dr. Niendorff present and Dr. Niendorff's insistence that she needed Ms. Bayles to help her manage her patient load.

175. CPS admits that the Board was aware of the ZPIC audit and the compliance committee review, but is without sufficient information as to whether all of the Owners knew of the details of the ZPIC audit and compliance committee review, and therefore, denies the same.

176. CPS admits that it availed itself of the Medicare Appeals process, to which all providers are entitled by law. CPS admits that the QIC reopened its Reconsideration Decision, and that CPS submitted additional documentation to the QIC in connection with that reopening. The remaining allegations in paragraph 176 are denied.

177. CPS admits that the QIC issued its Reconsideration Decision on September 1, 2016, reversing almost all of the denials and approving the medical necessity of all but a handful of claims, resulting in the original approximately \$27 million overpayment being reduced to an approximately \$6,900 overpayment.

178. CPS admits that on or about October 16 and 20, 2016, Cahaba notified CPS that seven East Tennessee providers associated with Smith's clinics (Anita Bayles, Christine Ladd, Dana Simpson, Jennifer Rose, Laura Godwin, Samantha Bryant and Tina Johnson) were being placed on prepayment review. CPS is without sufficient information concerning the reasons Cahaba decided to place these providers on prepayment review, and therefore, denies the same.

179. CPS states that, to the extent the allegations in paragraph 179 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 179, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

180. Denied.

181. Admitted.

182. Admitted.

183. Denied.

184. CPS admits that it notified providers that UDS orders are to be placed after the patient has been seen by the provider, and admits that it required providers to assess patients individually, but denies that this was a change as this was always CPS' policy.

185. CPS states that, to the extent the allegations in paragraph 185 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 185, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

186. Denied.

187. Denied.

188. CPS is without sufficient information regarding the allegations in paragraph 188, and therefore, denies the same.

189. CPS is without sufficient information regarding the allegations in paragraph 189, and therefore, denies the same.

d. Denied.

190. Denied.

191. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 195 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

192. Denied.

193. CPS denies that testing was done solely for the purpose of specimen validity testing, was not medically necessary, or lacked the requisite medical documentation. CPS is without sufficient information concerning the payment practices of Federal Healthcare Programs or TennCare, and therefore, denies the same.

194. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 194 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

195. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 195 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

196. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 196 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

197. CPS admits that the Owners and Davis sometimes shared in the profits from CPS' overall revenues, which did include revenue generated from UDS. The remaining allegations in paragraph 197 are denied.

198. CPS admits that Smith was entitled to share in a percentage of revenues, once clinic expenses were deducted, per the terms of his Employment Agreement with CPS, the terms of which speak for themselves.

i. Denied.

199. Denied.

200. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 200 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

201. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 5 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

202. Denied.

203. CPS denies that claims for specimen validity testing lacked the requisite medical documentation, were not medically necessary or did not satisfy standards for reimbursement. CPS is without sufficient information regarding the payment practices of Federal Healthcare Programs or TennCare, and therefore, denies the same.

204. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 204 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

205. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 205 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

206. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 206 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance. CPS denies that it or the Owners submitted any false claims.

ii. Denied.

207. Denied.

208. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 208 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

209. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 209 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

210. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 210 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

211. CPS denies that quantitative testing was not medically necessary or that it lacked the requisite medical documentation. CPS is without sufficient information regarding the payment practices of Federal Healthcare Programs or TennCare, and therefore, denies the same.

212. Denied.

213. CPS admits that its lab performed pharmacogenetic blood testing, as ordered by providers for treatment of patients. The remaining allegations in paragraph 213 are denied.

214. Denied.

215. The allegations in paragraph 215 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the cited sources speak for themselves and deny the allegations of Paragraph 215 to the extent they mischaracterize the sources' language, meaning, or application. CPS admits that CPT codes 81225, 81226, 81227, 81355, and 81401 are approved by CMS as molecular pathology procedure test codes. CPS denies that these codes are "non-specific procedure CPT codes," as they each relate to specific genetic aspects related to drug metabolism. The remaining allegations in paragraph 215 are denied.

216. The allegations in paragraph 216 purport to recite and characterize the terms of a written document, the content of which speaks for itself. To the extent the allegations in paragraph 216 mischaracterize the language, meaning or application of that written document, they are denied.

217. The allegations in paragraph 217 purport to characterize the terms of a written document, the content of which speaks for itself. To the extent the allegations in paragraph 217 mischaracterize the language, meaning or application of that written document, they are denied.

218. CPS states that, to the extent the allegations in paragraph 218 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 218, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

219. The allegations in paragraph 219 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the cited sources speak for themselves and denies the allegations of Paragraph 219 to the extent they mischaracterize the sources' language, meaning, or application.

220. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 220 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

221. Denied.

222. CPS admits that its compliance team educated providers on sample statements to provide examples of documentation required to demonstrate medical necessity in various instances. The remaining allegations in paragraph 222 are denied.

223. Admitted.

224. CPS states that, to the extent the allegations in paragraph 224 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 224, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

225. CPS states that, to the extent the allegations in paragraph 225 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 225, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

226. CPS admits that its compliance team worked to educate all providers on medical necessity and proper documentation, and instructed providers that genetic testing should not be ordered on all new patients in the absence of medical necessity. The remaining allegations in paragraph 226 are denied.

227. CPS states that, to the extent the allegations in paragraph 227 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 227, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

228. CPS states that, to the extent the allegations in paragraph 228 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 228, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

229. CPS admits that its compliance team discovered overutilization of genetic testing at clinics supervised by Dr. Donald Jones, and provided training to providers at those clinics as a result. The terms of Dr. Jones' contract with CPS speak for themselves, and CPS denies the

allegations in paragraph 229 to the extent that they are inconsistent with or mischaracterize the written contract.

230. Admitted.

231. Admitted.

232. CPS admits that Davis and Kroll received an email on November 11, 2015 from Pam Arnold. The November 11, 2015 email and attachments speak for themselves, and CPS denies the remaining allegations in paragraph 232 to the extent they are inconsistent with or mischaracterize those documents, their meaning or relevance. CPS is without sufficient information as to whether Davis or Kroll reviewed the November 11, 2015 email and its attachments, and therefore, denies the same.

233. CPS states that, to the extent the allegations in paragraph 233 reference the written minutes of the May 13, 2016 Compliance Committee meeting, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 233, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

234. Denied.

235. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 235 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

236. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 236 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

237. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 237 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

238. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 238 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

239. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 239 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

240. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 240 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance. CPS denies that it or the Owners submitted any false claims.

241. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 241 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

242. Denied.

243. The allegations in the first sentence of paragraph 243 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the cited sources speak for themselves and denies the allegations of Paragraph 243 to the extent they mischaracterize the sources' language, meaning, or application. As to the allegations in the second sentence, they appear to reference CPS' billing records, which billing records speak for themselves. CPS denies the allegations in paragraph 243 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

244. Denied.

245. CPS is without sufficient information regarding the feelings of all the dozens of providers who worked at CPS over the years on the issue of psychological testing, and therefore, denies the same. The remaining allegations in paragraph 245 are denied.

246. CPS admits that Davis created various bonus plans for mid-level providers employed by CPS over the years, which written documents speak for themselves.

247. Denied.

248. CPS states that, to the extent the allegations in paragraph 248 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 248, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

249. CPS states that its billing records and its Employment Agreement with Dr. Jones speak for themselves. CPS denies the allegations in paragraph 249 to the extent the allegations mischaracterize CPS' billing records or its Employment Agreement with Dr. Jones, their meaning or their relevance.

250. CPS states that, to the extent the allegations in paragraph 250 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 250, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

251. CPS states that, to the extent the allegations in paragraph 251 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 251, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

252. CPS states that, to the extent the allegations in paragraph 252 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 252, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

253. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 253 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

254. CPS is without sufficient information as to the allegations regarding Dickerson in paragraph 254, and therefore, denies the same.

255. Denied.

256. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 256 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

257. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 257 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

258. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 258 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance. CPS denies that it or the Owners submitted any false claims.

B. Denied.

259. Denied.

260. CPS admits that Davis adopted various employee bonus programs during his tenure as CEO, and that such employee bonus programs are written documents, the terms of which speak for themselves.

261. CPS admits that Davis adopted various employee bonus programs during his tenure as CEO, and that such employee bonus programs are written documents, the terms of which speak for themselves.

262. To the extent the allegations in paragraph 262 reference written documents, those documents speak for themselves. CPS admits that employee bonus spreadsheets were submitted primarily to Davis and Shannon Skipper.

263. CPS states that, to the extent the allegations in paragraph 263 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 263, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

264. CPS states that, to the extent the allegations in paragraph 264 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 264, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance. CPS denies that it incentivized any providers to order medically unnecessary services.

265. CPS is without sufficient information regarding what Ms. Trent acknowledged and in what context, and therefore, denies the same.

266. CPS states that, to the extent the allegations in paragraph 266 reference documents, the referenced documents speak for themselves. CPS denies the remaining allegations in paragraph 266, including to the extent that the allegations mischaracterize the documents, their meaning, or their relevance.

267. CPS admits that Dr. Pinson was employed in the Cleveland, Tennessee clinic that Smith oversaw. The remaining allegations reference Dr. Pinson's employment agreement, which is a written document which speaks for itself. CPS denies the remaining allegations in paragraph 267, including to the extent the allegations mischaracterize the employment agreement, its meaning, or its relevance.

268. CPS states that, to the extent the allegations in paragraph 268 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 268, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

269. CPS states that the allegations in paragraph 269 reference Dr. Buenger's employment agreement and CPS' financial records, which are written documents that speak for themselves. CPS denies the remaining allegations in paragraph 269, including to the extent that the allegations mischaracterize the documents, their meaning, or their relevance.

270. CPS states that, to the extent the allegations in paragraph 270 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 270, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

271. CPS admits that Smith oversaw the clinics in which Dr. Niendorff worked. CPS states that, to the extent the remaining allegations in paragraph 271 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 271, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

272. CPS admits that CPS physicians were compensated in part for referrals to CPS's pharmacy as part of the ancillary services revenue that was part of physician compensation. The remaining allegations in paragraph 272 are denied.

273. CPS states that, to the extent the allegations in paragraph 273 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 273, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

274. Denied.

275. CPS states that, to the extent the allegations in paragraph 275 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 275, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

276. CPS states that, to the extent the allegations in paragraph 276 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 276, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

277. CPS states that, to the extent the allegations in the first sentence of paragraph 277 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in the first sentence of paragraph 277, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance. CPS is without sufficient information regarding the allegations in the second sentence of paragraph 277, and therefore, denies the same.

278. CPS is without sufficient information regarding the allegations in paragraph 278, and therefore, denies the same.

279. Admitted.

280. CPS states that, to the extent the allegations in paragraph 280 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 280, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

281. Denied.

282. CPS admits that Smith improperly asserted pressure on some of the providers at his clinics to order certain services and devices, and for that reason, among others, CPS terminated Smith's Employment Agreement on June 27, 2017. The remaining allegations in paragraph 282 are denied.

283. CPS admits that Smith improperly asserted pressure on some of the providers at his clinics to order certain services and devices, and for that reason, among others, CPS terminated Smith's Employment Agreement on June 27, 2017.

284. Denied.

285. Admitted.

286. Denied.

C. Denied.

287. Denied.

288. CPS admits that around October 2013, Boyer, Skipper and Davis began working with external consultants regarding P-Stim. CPS denies that P-Stim is acupuncture.

289. Admitted. CPS affirmatively avers that all the Owners were educated on P-Stim.

290. CPS states that, to the extent the allegations in paragraph 290 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 290,

including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

291. CPS admits that National Coverage Determinations (“NCDs”) that address acupuncture have been issued, and that such NCDs are written documents which speak for themselves. CPS denies that P-Stim devices are acupuncture. The remaining allegations in paragraph 291 are denied.

292. Denied.

293. CPS admits that as of January 1, 2014, HCPCS code L8679 was used for implantable neurostimulator, pulse generator, any type. CPS denies the remaining allegations in paragraph 293.

294. The allegations of in the first sentence of paragraph 294 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the applicable statutes and regulations speak for themselves and denies the allegations in the first sentence of paragraph 294 to the extent they mischaracterize the statutes’ or regulations’ language, meaning, or application. CPS is without sufficient information regarding the allegations in the second sentence of paragraph 294, and therefore, denies the same.

295. CPS admits that NCDs that address electrical nerve stimulators have been issued, and that such NCDs are written documents which speak for themselves. CPS is without sufficient information to decipher the allegations in the first sentence of paragraph 295, and therefore, denies the same.

296. CPS admits that there are NCDs that address transcutaneous and percutaneous nerve stimulation, and that such NCDs are written documents which speak for themselves. CPS

denies the remaining allegations in paragraph 296, including to the extent that the allegations mischaracterize the cited NCDs, their meaning, or their relevance.

297. CPS admits that there are NCDs that address transcutaneous and percutaneous nerve stimulation, and that such NCDs are written documents which speak for themselves. CPS denies the remaining allegations in paragraph 297, including to the extent that the allegations mischaracterize the cited NCDs, their meaning, or their relevance.

298. Denied.

299. Denied.

300. CPS admits that billing issues were discussed internally and with various outside consultants. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 300 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

301. CPS states that, to the extent the allegations in paragraph 301 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 301, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

302. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 302 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

303. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 303 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

304. Denied.

305. CPS states that, to the extent the allegations in paragraph 305 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 305, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

306. CPS states that, to the extent the allegations in paragraph 306 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 306, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

307. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 307 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

308. CPS states that, to the extent the allegations in paragraph 308 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 308, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

309. CPS states that, to the extent the allegations in paragraph 309 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 309, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

310. CPS states that, to the extent the allegations in paragraph 310 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 310, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

311. CPS admits that its billing personnel would sometimes hold claims to determine proper billing, coding or documentation issues. To the extent the allegations in paragraph 311 also reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 311, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

312. CPS denies the allegations in the first sentence of paragraph 312. As to the allegations in the second sentence of paragraph 312, CPS states that its billing records speak for themselves. CPS denies the allegations in in the second sentence of paragraph 312 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

313. CPS states that, to the extent the allegations in paragraph 313 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 313, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

314. CPS states that, to the extent the allegations in paragraph 314 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 314, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

315. CPS states that, to the extent the allegations in paragraph 315 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 315, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

316. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 316 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

317. CPS states that, to the extent the allegations in paragraph 317 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 317, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

318. CPS states that, to the extent the allegations in paragraph 318 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 318, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

319. CPS states that, to the extent the allegations in paragraph 319 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 319, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

320. CPS denies the allegations in paragraph 320 as a mischaracterization of a written March 31, 2014 email, the content of which speaks for itself.

321. Denied.

322. CPS admits that its compliance personnel conducted an internal audit of P-Stim claims in 2014. The remaining allegations in paragraph 322 are denied.

323. CPS states that, to the extent the allegations in paragraph 323 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 323,

including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

324. CPS states that, to the extent the allegations in paragraph 324 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 324, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

325. CPS states that, to the extent the allegations in paragraph 325 reference the internal audit documents prepared by CPS compliance personnel in 2014 regarding P-Stim claims, such documents speak for themselves. CPS denies the remaining allegations in paragraph 325, including to the extent that the allegations mischaracterize the documents, their meaning, or their relevance.

326. CPS states that, to the extent the allegations in paragraph 326 reference the internal audit documents prepared by CPS compliance personnel in 2014 regarding P-Stim claims, such documents speak for themselves. CPS denies the remaining allegations in paragraph 326, including to the extent that the allegations mischaracterize the documents, their meaning, or their relevance.

327. Admitted.

328. CPS states that, to the extent the allegations in paragraph 328 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 328, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

329. Denied.

330. Denied.

331. CPS is without sufficient information regarding the allegations in the first sentence of paragraph 331, and therefore, denies the same. As to the allegations in the second sentence of

paragraph 331, to the extent those allegations reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 331, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

332. CPS states that, to the extent the allegations in paragraph 332 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 332, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

333. Denied.

334. CPS denies the allegations in the first sentence of paragraph 334. As to the allegations in the second sentence of paragraph 334, CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 334 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

335. CPS admits that from 2006 until May 2011, when Davis became CEO of CPS, Kroll was responsible for hiring medical providers and providing initial review of clinical policies and procedures related to pain management. CPS admits that Kroll has provided training to many CPS providers over the years, and that Muench shadowed Kroll when he was first hired in 2011. The remaining allegations in paragraph 335 are denied.

336. Denied.

337. CPS states that, to the extent the allegations in paragraph 337 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 337, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

338. The allegations of in the first sentence of paragraph 338 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the applicable Medicaid/TennCare statutes and regulations speak for themselves and denies the allegations in the first sentence of paragraph 338 to the extent they mischaracterize the statutes' or regulations' language, meaning, or application. The allegations in the second sentence of paragraph 338 are denied. CPS is without sufficient information regarding the allegations in the third sentence of paragraph 338, and therefore, denies the same.

339. Denied.

340. CPS states that, to the extent the allegations in paragraph 340 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 332, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance. CPS is without sufficient information as to the ownership of Ascend Medical Group, LLC, and therefore, denies the allegations regarding same.

341. CPS is without sufficient information regarding the allegations in paragraph 341, and therefore, denies the same.

342. Denied.

343. Denied.

344. Denied.

345. CPS states that, to the extent the allegations in the first sentence of paragraph 345 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in the first sentence of paragraph 345, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance. As to the remaining allegations in paragraph 345, CPS states that its billing records speak for themselves. CPS denies the remaining

allegations in paragraph 345 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

346. Denied.

347. Denied.

348. CPS denies the allegations in the first sentence of paragraph 348. As to the allegations in the second sentence of paragraph 348, to the extent those allegations reference a documents, the referenced document speaks for itself. CPS denies the remaining allegations in the second sentence of paragraph 348, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

349. CPS denies the allegations in the last sentence of paragraph 349. CPS states that, to the extent the remaining allegations in paragraph 349 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 349, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

350. Denied.

351. CPS states that its billing records speak for themselves. CPS denies the allegations in the first sentence of paragraph 351 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance. CPS denies the allegations in the second sentence of paragraph 351.

352. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 352 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

353. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 353 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

354. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 354 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

355. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 355 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

356. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 356 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance. CPS affirmatively avers that Kroll was the medical director of the CPS lab, which rendered the lab services CPS billed to payors, and therefore, the lab claims were appropriately billed with Kroll's NPI as the rendering provider.

357. Denied.

358. CPS is without sufficient information regarding the allegations in paragraph 358, and therefore, denies the same.

359. Denied.

360. The allegations in paragraph 360 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the cited statute speaks for itself and denies the allegations in paragraph 360 to the extent they mischaracterize the statute's language, meaning, or application.

361. The allegations in paragraph 361 are legal conclusions to which no response is required. To the extent that a response is required, CPS states that the cited statute speaks for itself and denies the allegations in paragraph 361 to the extent they mischaracterize the statute's language, meaning, or application.

362. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 362 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

363. Denied.

E. Denied.

364. Denied.

365. Admitted.

366. Denied.

367. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 367 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

368. CPS states that its financial records speak for themselves. CPS denies the allegations in paragraph 368 to the extent the allegations mischaracterize CPS' financial records, their meaning or their relevance.

369. CPS admits the allegations in the first sentence of paragraph 369. To the extent the allegations in the second sentence of paragraph 369 refer to the written minutes of the January 5, 2016 Board Meeting, those meeting minutes speak for themselves. CPS denies the remaining allegations in paragraph 369, including to the extent that the allegations mischaracterize the meeting minutes, its meaning, or its relevance.

370. Admitted.

371. CPS states that its financial records speak for themselves. CPS denies the allegations in paragraph 371 to the extent the allegations mischaracterize CPS' financial records, their meaning or their relevance.

372. CPS states that its financial records speak for themselves. CPS denies the allegations in paragraph 372 to the extent the allegations mischaracterize CPS' financial records, their meaning or their relevance.

373. Denied.

374. Denied.

375. Denied.

376. CPS states that, to the extent the allegations in paragraph 376 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 376, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

377. CPS states that, to the extent the allegations in paragraph 377 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 377, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

378. CPS admits that Kroll has served as CPS' Chief Medical Officer and as a member of its compliance committee. The remaining allegations in paragraph 378 are denied.

VII. Denied

379. CPS admits that Davis made the decision to fire over 80 employees at the Gallatin Operations Center. The remaining allegations in paragraph 379 are denied.

380. CPS states that, to the extent the allegations in paragraph 380 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 380, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

381. CPS is without sufficient information regarding Davis' hopes, and therefore, denies the same.

382. Admitted.

383. CPS admits that Novitas instituted a payment suspension effective August 21, 2017, but denies that the payment suspension means CPS could no longer receive Medicare reimbursement from Novitas. Rather, CPS affirmatively avers that the Medicare reimbursement to which CPS is entitled is placed in a suspension account by Novitas pending resolution of Novitas' post-payment review of CPS' claims, after which the funds in the suspension account must be released to CPS after deducting any overpayment that may be determined through the post-payment review, which overpayment, if any, CPS may appeal through the Medicare Appeals Process.

384. Denied.

385. Denied.

386. Admitted.

387. CPS states that, to the extent the allegations in paragraph 387 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 387, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

388. Denied.

389. Denied.

390. CPS states that its financial records speak for themselves. CPS denies the allegations in paragraph 390 to the extent the allegations mischaracterize CPS' financial records, their meaning or their relevance.

391. CPS states that its financial records speak for themselves. CPS denies the allegations in paragraph 391 to the extent the allegations mischaracterize CPS' financial records, their meaning or their relevance.

392. CPS states that its financial records speak for themselves. CPS denies the allegations in paragraph 392 to the extent the allegations mischaracterize CPS' financial records, their meaning or their relevance.

393. CPS states that its financial records speak for themselves. CPS denies the allegations in paragraph 371 to the extent the allegations mischaracterize CPS' financial records, their meaning or their relevance.

394. CPS states that its financial records speak for themselves. CPS denies the allegations in paragraph 394 to the extent the allegations mischaracterize CPS' financial records, their meaning or their relevance.

395. CPS states that its financial records speak for themselves. CPS denies the allegations in paragraph 395 to the extent the allegations mischaracterize CPS' financial records, their meaning or their relevance.

396. CPS states that its financial records speak for themselves. CPS denies the allegations in paragraph 396 to the extent the allegations mischaracterize CPS' financial records, their meaning or their relevance.

397. CPS states that its financial records speak for themselves. CPS denies the allegations in paragraph 397 to the extent the allegations mischaracterize CPS' financial records, their meaning or their relevance.

398. CPS states that its financial records speak for themselves. CPS denies the allegations in paragraph 398 to the extent the allegations mischaracterize CPS' financial records, their meaning or their relevance.

399. CPS states that its financial records speak for themselves. CPS denies the allegations in paragraph 399 to the extent the allegations mischaracterize CPS' financial records, their meaning or their relevance.

400. CPS states that its financial records speak for themselves. CPS denies the allegations in paragraph 400 to the extent the allegations mischaracterize CPS' financial records, their meaning or their relevance.

401. Denied.

402. CPS admits it did not place any funds in escrow for the benefit of the United States, but denies that it had any obligation to do so.

403. Denied.

VIII. Denied.

404. CPS is without sufficient information as to whether each of the Defendants was fully aware of all of the requirements for participation in Federal Healthcare Programs and TennCare, and therefore, denies the same.

405. Admitted.

406. CPS states that, to the extent the allegations in paragraph 406 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 406,

including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

407. CPS states that, to the extent the allegations in paragraph 407 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 407, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

408. CPS is without sufficient information as to whether Smith was enrolled in Medicare, and therefore, denies the same.

409. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 409 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

410. CPS states that, to the extent the allegations in paragraph 410 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 410, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

411. CPS states that, to the extent the allegations in paragraph 411 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 411, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

412. CPS states that, to the extent the allegations in paragraph 412 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 412, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

413. CPS states that, to the extent the allegations in paragraph 413 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 413, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

414. CPS states that, to the extent the allegations in paragraph 414 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 414, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

415. Denied.

416. Admitted.

417. CPS states that, to the extent the allegations in paragraph 417 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 417, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

418. Denied.

IX. Denied.

419. Denied.

420. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 420 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

421. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 421 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

422. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 422 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

423. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 423 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

424. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 424 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

425. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 425 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

426. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 426 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

427. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 427 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

428. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 428 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

429. CPS states that its billing records speak for themselves. CPS denies the allegations in paragraph 429 to the extent the allegations mischaracterize CPS' billing records, their meaning or their relevance.

430. CPS states that, to the extent the allegations in paragraph 430 reference a document, the referenced document speaks for itself. CPS denies the remaining allegations in paragraph 430, including to the extent that the allegations mischaracterize the document, its meaning, or its relevance.

431. The allegations in paragraph 431 are legal conclusions to which no response is required. To the extent a response is required, CPS denies any characterization of the applicable laws and states that the applicable laws speak for themselves.

432. Denied.

433. Denied.

434. CPS incorporates its responses to Paragraphs 1 through 433 above as though fully set forth here in response to Paragraph 434.

435. Denied.

436. Denied.

437. Denied.

438. Denied.

439. CPS incorporates its responses to Paragraphs 1 through 438 above as though fully set forth here in response to Paragraph 439.

440. Denied.

441. Denied.

442. Denied.

443. Denied.

444. Denied.

445. CPS incorporates its responses to Paragraphs 1 through 444 above as though fully set forth here in response to Paragraph 435.

446. Denied.

447. Denied.

448. Denied.

449. CPS incorporates its responses to Paragraphs 1 through 448 above as though fully set forth here in response to Paragraph 449.

450. Denied.

451. Denied.

452. Denied.

453. CPS incorporates its responses to Paragraphs 1 through 452 above as though fully set forth here in response to Paragraph 453.

454. Denied.

455. Denied.

456. Denied.

457. Denied.

458. Denied.

459. Denied.

460. Denied.

461. Denied.

462. CPS incorporates its responses to Paragraphs 1 through 461 above as though fully set forth here in response to Paragraph 462.

463. Denied.

464. Denied.

465. Denied.

466. Denied.

467. CPS incorporates its responses to Paragraphs 1 through 466 above as though fully set forth here in response to Paragraph 467.

468. Denied.

469. Denied.

470. Denied.

471. CPS incorporates its responses to Paragraphs 1 through 470 above as though fully set forth here in response to Paragraph 471.

472. Denied.

473. Denied.

474. Denied.

475. Denied.

476. Denied.

477. Denied.

Denial of All Allegations Not Otherwise Admitted

CPS denies each and every allegation of the Complaint not specifically admitted herein.

Prayer for Relief

CPS denies that the United States or the State of Tennessee is entitled to any of the relief set forth in their prayer for relief.

DEMAND FOR JURY TRIAL

CPS demands a trial by jury on all triable issues.

AFFIRMATIVE DEFENSES

First Defense

The United States' and the State of Tennessee's claims are barred in whole or in part by the affirmative defense of accord and satisfaction.

Second Defense

The United States' and the State of Tennessee's claims are barred in whole or in part by the affirmative defense of estoppel.

Third Defense

The United States' and the State of Tennessee's claims are barred in whole or in part by the affirmative defense of laches.

Fourth Defense

The United States' and the State of Tennessee's claims are barred in whole or in part by the affirmative defense of waiver.

Fifth Defense

The United States and the State of Tennessee's claims are barred in whole or in part by the affirmative defense of release.

Sixth Defense

The United States' and the State of Tennessee's claims are barred in whole or in part by the affirmative defense of statute of limitations or repose.

Seventh Defense

The United States' and the State of Tennessee's claims fail because, over the time period alleged in the Complaint, there was no clear, unambiguous, or objective legal standard by which to judge truth or falsity of the claims at issue.

Eighth Defense

The United States' and the State of Tennessee's claims fail because there are legitimate clinical disagreements where reasonable medical judgment could differ as to whether the claims at issue were reasonable and medically necessary.

Ninth Defense

The United States' and the State of Tennessee's claims fail, in whole or in part, because CPS' patients' needs were solely determined by the clinicians who treated the patients in the exercise of their independent, professional judgment.

Tenth Defense

The United States' and the State of Tennessee's claims fail because, to the extent any claim is deemed to have been made for non-covered services, CPS did not make the claim with knowledge that the services were not covered and did not act in reckless disregard or with deliberate indifference of the claim's validity.

Eleventh Defense

The United States' and the State of Tennessee's claims fail, in whole or in part, because the alleged non-covered services, and the claims, statements, and records pertaining to those alleged services, were not material to the amount the government paid for the claims.

Twelfth Defense

The United States' and the State of Tennessee's claims are barred for failure to mitigate damages.

Thirteenth Defense

The United States' and the State of Tennessee's claims are barred or lessened by any claim amounts that the United States' and/or the State of Tennessee recouped or underpaid.

Fourteenth Defense

The United States and the State of Tennessee is barred from obtaining relief against CPS because CPS' conduct was at all times reasonable, proper, in good faith, and in compliance with applicable law.

Fifteenth Defense

At no time did CPS act with malicious, willful, wanton, or reckless intent to violate any statute or law.

Sixteenth Defense

CPS never knowingly presented a false or fraudulent claim for payment or approval.

Seventeenth Defense

Some or all of the purported claims and allegations in the Complaint are barred because they amount to differences of subjective medical, clinical, and scientific opinions that do not create or establish violations of the False Claims Act or the Tennessee Medicaid False Claims Act.

Eighteenth Defense

CPS never knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim.

Nineteenth Defense

The Complaint is barred, in whole or in part, because the government's knowledge of the facts underlying the allegedly false claims negates the scienter, falsity, and materiality requirements of the False Claims Act.

Twentieth Defense

The Complaint is barred because CPS' actions were taken in good faith and in reasonable reliance upon regulatory interpretations and judgments by the Government and its agents and contractors upon whom CPS was entitled to rely.

Twenty-First Defense

The Complaint fails to establish the elements necessary for recovery under the False Claims Act, the Tennessee Medicaid False Claims Act, the Federal Priority Statute and doctrines of unjust enrichment, payment by mistake or common law fraud.

Twenty-Second Defense

The Complaint fails to establish that CPS is vicariously liable for the actions taken by its employees, agents, contractors, or third parties.

Twenty-Third Defense

The Complaint fails to establish that the Government sustained damages because of CPS' actions.

Twenty-Fourth Defense

The Complaint is barred, in whole or in part, because the United States' and the State of Tennessee's case violates CPS' constitutional rights to due process.

Twenty-Fifth Defense

The Complaint fails to state a claim against CPS.

Twenty-Sixth Defense

The United States' and the State of Tennessee's claims fail to the extent they do not identify with specificity (e.g., by dates, patients, persons engaged in allegedly fraudulent conduct, etc.) the alleged false claims.

Twenty-Seventh Defense

The United States' and the State of Tennessee's claims should be reduced, modified and/or barred by the Doctrine of Unclean Hands.

Twenty-Eighth Defense

The United States' and the State of Tennessee's False Claims Act claims are barred in whole or in part by the Public Disclosure bar of the False Claims Act, and this Court lacks jurisdiction over such claims.

Twenty-Ninth Defense

CPS' conduct was not the proximate cause of the alleged injuries or damages, if any.

Thirtieth Defense

The United States and the State of Tennessee have failed to plead fraud with the adequate degree of specificity and particularity as required by applicable statutory and/or common law.

Thirty-First Defense

The United States' and the State of Tennessee's claims are barred because CPS, at all times relevant hereto, complied with all applicable laws and regulations.

Thirty-Second Defense

The United States' and the State of Tennessee's claims are barred by the doctrines of res judicata/collateral estoppel to the extent they seek to recover for the same claims that were the subject of the ZPIC Audit and subsequent Medicare Appeals Process.

CPS reserves the right to amend this Answer to include any additional defense which may become known or available during this litigation.

Respectfully Submitted,

/s/ Jennifer L. Weaver

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CERTIFICATE OF SERVICE

I hereby certify that on September 23, 2019, I caused a true and correct copy of the foregoing document to be filed with the Court's CM/ECF system, which will send notification of such filing to the following counsel of record:

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